

**OFICIO 3000-0346-24**

Bogotá D.C., marzo de 2024

**Asunto:** Acuso Recibo de Eventos Adversos Serios

Dando cumplimiento a lo estipulado en la Resolución No. 2011020764 del 10 de junio de 2011 “*Por la cual se establece el reglamento relativo al contenido y periodicidad de los reportes de eventos adversos en la fase clínica con medicamentos en humanos de que trata el artículo 146 del decreto 677 de 1995*”, la Dirección de Medicamentos y Productos Biológicos del **Invima**, da acuso de recibo de la información allegada con los siguientes radicados, correspondientes al reporte de eventos adversos serios nacionales e internacionales y otros documentos relacionados. El Invima en cualquier momento y como parte del proceso de análisis de la información, podrá requerir datos adicionales, para efectos de Inspección, Vigilancia y Control.

**Eventos Adversos Serios Nacionales**

<b>RADICADO</b>	<b>FECHA RADICADO</b>	<b>PATROCINADOR o CRO</b>	<b>CODIGO INVIMA</b>
20201152666	2020-08-31	Bayer S.A.	PI-BH-1012
20201152698	2020-08-31	Bayer S.A.	PI-BH-776
20201152735	2020-08-31	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201152775	2020-08-31	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201152802	2020-08-31	Bayer S.A.	PI-BH-1012
20201152940	2020-08-31	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201153006	2020-08-31	Eli Lilly and Company / PPD Colombia S.A.S.	PI-EL-1257
20201153389	2020-09-01	Amgen Inc. / IQVIA RDS COLOMBIA SAS	PI-AG-1115
20201237246	2020-12-11	Bayer S.A.	PI-BH-1012

20211003636	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20201241431	2020-12-16	Bayer S.A.	PI-BH-1012
20211002318	2021-01-08	Bayer S.A.	PI-BH-1012
20211003193	2021-01-12	Bayer S.A.	PI-BH-1012
20211003208	2021-01-12	Bayer S.A.	PI-BH-773
20211003216	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003220	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003256	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003274	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003280	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003477	2021-01-12	Bayer S.A.	PI-BH-1012
20211003547	2021-01-12	Bayer S.A.	PI-BH-1012
20211003546	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003568	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003622	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003644	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419

20211003656	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003862	2021-01-13	IQVIA RDS COLOMBIA S.A.S.	PI-BIG-1180
20211003805	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003810	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003814	2021-01-12	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211003821	2021-01-12	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211003933	2021-01-13	Janssen Vaccines & Prevention B.V.	PI-JC-1419
20211004168	2021-01-13	Bayer S.A.	PI-BH-1012
20211004218	2021-01-13	Bayer S.A.	PI-BH-1012
20211004223	2021-01-13	Bayer S.A.	PI-BH-1012

### Eventos Adversos Serios Internacionales

RADICADO	FECHA RADICADO	PATROCINADOR o CRO	CODIGO INVIMA
20211001062	2021-01-05	Bristol Myers Squibb de Colombia S.A.	Patrocinador

20201152907	2020-08-31	Kinex Pharmaceuticals Inc / Athenex – Cidal Colombia S.A.S.	PI-KP-1106
20201153044	2020-08-31	Human genome Sciences, Inc. / PAREXEL International Colombia S.A.S.	PI-HGS-726
20201153057	2020-08-31	Regeneron Pharmaceuticals, Inc. / ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-RPH-1089
20201153201	2020-08-31	Kezar Life Sciences / INC Research Colombia Ltda.	PI-UL-1281
20201153216	2020-08-31	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20201153219	2020-08-31	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1271
20201154087	2020-09-01	P-(FH) F. Hoffmann- La Roche Ltd. / IQVIA RDS COLOMBIA SAS	PI-FH-975
20201236827	2020-12-10	AstraZeneca / RPS Colombia LTDA (Compañía del grupo PRA Health Sciences).	PI-AZ-1170

20201243835	2020-12-17	Boston pharmaceuticals, Inc. / INC Research Colombia Ltda.	PI-BT-1255
20201244123	2020-12-18	Apellis Pharmaceutical, Inc. / Intriols S.A.S.	PI-AL-1304
20201153197	2020-08-31	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211003199	2021-01-12	Bristol Myers Squibb de Colombia S.A.	PI-BM-745
20211001064	2021-01-05	Bristol Myers Squibb de Colombia S.A.	PI-BM-1202
20211003229	2021-01-12	GENFIT / Labcorp Colombia Services LTDA.	PI-GF-1078
20201237240	2020-12-11	GlaxoSmithKline Colombia S.A	PI-GS-1414
20211003290	2021-01-12	Bristol Myers Squibb de Colombia S.A.	Patrocinador
20211003301	2021-01-12	Bristol Myers Squibb de Colombia S.A.	PI-BM-1202
20211003398	2021-01-12	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267

20211003529	2021-01-12	Regeneron Pharmaceuticals, Inc. / ICON Holdings Clinical Research International Limited Sucursal Colombia	PI-RPH-1185
20211003580	2021-01-12	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1270
20211003600	2021-01-12	ACADIA Pharmaceuticals Inc. / Worldwide Clinical Trials Colombia SAS (Antes Worldwide Clinical Trials Sucursal Colombia)	PI-ADP-1270
20211003727	2021-01-12	Allergan Sales, LLC (anteriormente Durata Therapeutics International B.V. un Socio de Allergan) / Syneos Health Colombia Ltda.	PI-DT-1138
20211004186	2021-01-12	Sarepta Therapeutics, Inc/PPD Colombia S.A.S.	PI-ST-1324
20211003807	2021-01-12	SYNEOS HEALTH	PI-AR-1208
20211003825	2021-01-12	Biogen	PI-BG-1104
20211003828	2021-01-12	Genzyme Corporation/PPD Colombia S.A.S.	PI-GE-1365
20211003830	2021-01-12	Discovery Laboratorios, Inc	PI-DI-1039
20211003876	2021-01-12	IQVIA RDS COLOMBIA S.A.S.	P1-MEI-1331

20211003996	2021-01-12	Actelion Pharmaceuticals Ltd	PI-AC-1227
20211004016	2021-01-12	Biogen	PI-BG-1313
20211003819	2021-01-12	Acerta Pharma, BV / PPD Colombia S.A.S	PI-ACE-1000
20211003817	2021-01-12	AstraZeneca	PI-AZ-1337
20211003842	2021-01-12	P-(MP) Millennium Pharmaceuticals, Inc. / PPD Colombia S.A.S.	PI-MP-969
20211003846	2021-01-13	GlaxoSmithkline Research & Development Limited / PPD Colombia S.A.S.	PI-GS-1132
20211003853	2021-01-13	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1216
20211003858	2021-01-13	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1216
20211003866	2021-01-13	Kowa Research Institute, Inc. / IQVIA RDS COLOMBIA SAS	PI-KW-1124
20211003872	2021-01-13	Esperion Therapeutics, Inc. / IQVIA RDS COLOMBIA SAS	PI-ET-1127

20211003945	2021-01-13	AstraZeneca	PI-AZ-1245
20211003966	2021-01-13	Astellas Pharma Global Development, Inc. / PAREXEL International Colombia S.A.S.	PI-AS-1267
20211004160	2021-01-13	Celgene Corporation / PPD Colombia S.A.S.	PI-CC-1166
20211004194	2021-01-13	Shire Human Genetic Therapies Inc. / PPD Colombia S.A.S.	PI-SH-1226
20211004232	2021-01-13	Shire Human Genetic Therapies, Inc. (Shire) / PPD Colombia S.A.S	PI-SH-1216
20211004268	2021-01-13	Human genome Sciences, Inc. / IQVIA RDS COLOMBIA SAS	PI-HGS-723
20211004396	2021-01-13	R-Pharm / IQVIA RDS COLOMBIA SAS	Patrocinador

Atentamente,

**LIGIA LORENA RODRIGUEZ MUÑOZ**

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Proyectó: Grupo de Investigación Clínica